

VICETON- chloramphenicol tablet, coated Osborn

DESCRIPTION:

Chloramphenicol is a broad-spectrum antibiotic shown to have specific therapeutic activity against a wide variety of organisms. Its activity was first demonstrated in culture filtrates from a species of soil organism collected in Venezuela, later designated as ***Streptomyces venezuelae***. The antibiotic was subsequently isolated from culture filtrates (1), identified chemically (2), and later synthesized (3).

Aqueous solutions of chloramphenicol are neutral in pH. Chloramphenicol is stable for several years at room temperature and forms colorless to yellowish-white crystals in the shape of elongated plates or fine needles. It is only slightly soluble in water, but soluble in alcohol and propylene glycol.

Chloramphenicol is exceptionally stable in the presence of high pH, although it is destroyed at pH's in excess of 10. Dissolved in distilled water, it can withstand boiling for five hours (1).

ACTIONS:

At low concentrations, chloramphenicol exerts a bacteriostatic effect on a wide range of pathogenic organisms, including many Gram-positive and Gram-negative bacteria, spirochetes, several rickettsia and certain large viruses and Mycoplasma (PPLO) (4,5,6,7,8,9,10,11,12,13, and 13a). At high concentrations, it inhibits growth of animal and plant cells.

Chloramphenicol exerts its bacteriostatic action by inhibiting protein synthesis in susceptible organisms. Complete suppression of the assimilation of ammonia and of the incorporation of amino acids, particularly glutamic acid, together with an increased formation of ribonucleic acid (RNA), lead to an inhibition of bacterial growth (4, 14, 15, 16, and 17).

Chloramphenicol antagonizes the action of such antibiotics as penicillin and streptomycin, which act only on growing cells, but is synergistic to tetracycline, which also acts by inhibiting protein synthesis. (18) It is possible the chloramphenicol would produce similar synergism with other antibiotics which act by inhibiting protein synthesis.

In this respect, the experimentally demonstrated synergistic action between chloramphenicol and gamma-globulin should be mentioned. Clinical observations in man and corresponding investigations in laboratory animals experimentally infected with various pathogenic bacteria have shown that a combination of chloramphenicol with gamma-globulin or specific antisera has a greater therapeutic effect than would be expected from a mere addition of the individual effects (19,20, 21, and 22).

Many experiments have revealed that the development of resistance to chloramphenicol is rare compared with that occurring with other important antibiotics. (23,24, 25, 26, 27, 28, 29, 30, 31, 32, 33, and 34) Bacterial resistance may develop in some strains against chloramphenicol but has been encountered only infrequently in clinical usage.

Chloramphenicol achieves maximum serum levels very rapidly following oral, intravenous and intraperitoneal administration. Intramuscular injection with chloramphenicol, except certain soluble forms, results in a somewhat delayed absorption and lower serum levels than when given by the oral, intravenous, or intraperitoneal route.

Chloramphenicol diffuses readily into all body tissues, but at different concentrations. Highest concentrations are found in the liver and kidney of dogs indicating that these organs are the main route of inactivation and excretion of the metabolites. The lungs, spleen, heart and skeletal muscles contain concentrations similar to that of the blood (27, 35, 36, 37, 38, and 39).

Chloramphenicol reaches significant concentration in the aqueous and vitreous humors of the eye from the blood (4).

A significant difference from other antibiotics is its marked ability to diffuse into the cerebrospinal

fluid. Within three to four hours after administration, the concentration in the cerebrospinal fluid has reached, on the average, 50% of the concentration in the serum. If the meninges are inflamed, the percentage may be even higher (4, 27, 29, 40, 41, 42, and 43).

Chloramphenicol diffuses readily into milk, pleural and ascitic fluids and crosses the placenta attaining concentrations of about 75% of that of the maternal blood (36 and 44).

Chloramphenicol is rather rapidly metabolized, mainly in the liver, by conjugation with glucuronic acid.

Approximately 55% of a single daily dose can be recovered from the urine of a treated dog. A small fraction of this is in the form of unchanged chloramphenicol (36).

A single intravenous dose of 150 mg/kg (approximately 68 mg/lb) in propylene glycol is the maximum dose tolerated by the dog. (45) No toxic effect was observed when dogs were administered orally, 200 mg/kg (approximately 91 mg/lb) daily for over four months. (40) In the mouse, the LD-50 is 150-250 mg/kg (68 to 114 mg/lb) body weight by intravenous injection and 1,500 mg/kg (approximately 681 mg/lb) by the oral administration (1 and 46).

INDICATIONS:

Chloramphenicol Tablets are recommended for oral treatment of the following conditions in dogs:

- Bacterial pulmonary infections caused by susceptible microorganisms such as: *Staphylococcus aureus*, *Streptococcus pyogenes* and *Brucella bronchiseptica*.
- Infections of the urinary tract caused by susceptible microorganisms such as: *Escherichia coli*, *Proteus vulgaris*, *Corynebacterium renale*, *Streptococcus* spp., and hemolytic *Staphylococcus*.
- Enteritis caused by susceptible microorganisms such as: *E. coli*, *Proteus* spp., *Salmonella* spp., and *Pseudomonas* spp.
- Infections associated with canine distemper caused by susceptible microorganisms such as: *B. bronchiseptica*, *E. coli*, *P. aeruginosa*, *Proteus* spp., *Shigella* spp. and *Neisseria catarrhalis*.

Additional adjunctive therapy should be used when indicated. Most susceptible infectious disease organisms will respond to chloramphenicol therapy in three to five days when the recommended dosage regimen is followed. If no response to chloramphenicol therapy is obtained in three to five days, discontinue its use and review the diagnosis. Also, a change of therapy should be considered.

Laboratory tests should be conducted including *in vitro* culturing and susceptibility tests on samples collected prior to treatment.

CONTRAINDICATIONS:

Because of potential antagonism, chloramphenicol should not be administered simultaneously with penicillin or streptomycin.

WARNING:

NOT FOR USE IN ANIMALS WHICH ARE RAISED FOR FOOD PRODUCTION.
CHLORAMPHENICOL PRODUCTS SHOULD NOT BE ADMINISTERED IN CONJUNCTION WITH OR 2 HOURS PRIOR TO THE INDUCTION OF GENERAL ANESTHESIA WITH PENTOBARBITAL BECAUSE OF PROLONGED RECOVERY.

CHLORAMPHENICOL SHOULD NOT BE ADMINISTERED TO DOGS MAINTAINED FOR BREEDING PURPOSES. SOME EXPERIMENTS INDICATE THAT CHLORAMPHENICOL CAUSES IN EXPERIMENTAL ANIMALS, PARTICULARLY IN FEMALES, SIGNIFICANT DISORDERS IN MORPHOLOGY AS WELL AS IN FUNCTION OF THE GONADS.

HAZARDS AND PRECAUTIONS:

1. This antibiotic contains a chemical structure (nitrobenzene group) that is characteristic of a group of drugs long known to depress hematopoietic activity of the bone marrow (54).

2. *In vitro*-tissue culture studies using canine bone marrow cells have demonstrated that extremely high concentrations of chloramphenicol inhibit both uptake of iron by the nucleated red cells and incorporation of iron into heme (55).
3. Chloramphenicol products should not be administered in conjunction with or two hours prior to the induction of general anesthesia with pentobarbital because of prolonged recovery time.
4. Chloramphenicol products should not be administered to dogs maintained for breeding purposes. Some experiments indicate that chloramphenicol causes, in experimental animals, particularly females, significant disorders in morphology as well as in function of the gonads.

ADVERSE REACTIONS:

Certain individual dogs may exhibit transient vomiting or diarrhea after an oral dose of 25 mg/lb body weight (49).

DOSAGE AND ADMINISTRATION:

Dogs-25 mg/lb body weight every 6 hours for oral administration.

CAUTION:

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Keep out of reach of children.

Store at or below 25°C (77°F) in a dry place.

HOW SUPPLIED:

250 mg.....Bottles of 500's, 1000's

500 mg.....Bottles of 500's

1 gram.....Bottles of 100's

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Chloramphenicol should not be administered to dogs maintained for breeding purposes. Some experiments indicate that chloramphenicol causes in experimental animals, particularly in females, significant disorders in morphology as well as in function of the gonads.

TAKE TIME  OBSERVE LABEL DIRECTIONS



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Manufactured by: Bimeda, Inc.
Le Sueur, MN 56058

Product No. 1VIC005
8VIC005-1104

Viceton®

Chloramphenicol

500 mg Tablets

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

NADA 055-059, Approved by FDA

NET CONTENTS:
500 Tablets (500 mg each)

Osborn®

INDICATIONS: Viceton (chloramphenicol) tablets are indicated for treatment of the following conditions in dogs caused by chloramphenicol susceptible microorganisms: Bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections and bacterial infections of the urinary tract.

DOSAGE: Dogs-25 mg/lb body weight every 6 hours via oral administration.

WARNING: Not for use in animals which are raised for food production. Chloramphenicol products should not be administered in conjunction with or 2 hours prior to the induction of general anesthesia with pentobarbital because of prolonged recovery.

Read package insert carefully before use.
Store at or below 25°C (77°F) in a dry place.

LOT:
EXP:

Chloramphenicol should not be administered to dogs maintained for breeding purposes. Some experiments indicate that chloramphenicol causes in experimental animals, particularly in females, significant disorders in morphology as well as in function of the gonads.



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Manufactured by:
Bimeda, Inc.
Le Sueur, MN 56058

Product No. 1VIC004
8VIC004-1104

Viceton®

Chloramphenicol

250 mg tablets

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

NADA 055-059, Approved by FDA

NET CONTENTS: 500 Tablets
(250 mg each)

Osborn®

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Read package insert carefully before use.

Store at or below 25°C (77°F) in a dry place.

LOT:
EXP:

Chloramphenicol should not be administered to dogs maintained for breeding purposes. Some experiments indicate that chloramphenicol causes in experimental animals, particularly in females, significant disorders in morphology as well as in function of the gonads.



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Manufactured by:
Bimeda, Inc.
Le Sueur, MN 56058

Product No. 1VIC002
8VIC002-1104

Viceton®

Chloramphenicol

1 Gram Tablets

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

NADA 055-059, Approved by FDA

NET CONTENTS: 100 Tablets
(1 Gram each)

Osborn®

INDICATIONS: Viceton (chloramphenicol) tablets are indicated for treatment of the following conditions in dogs caused by chloramphenicol susceptible microorganisms: Bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections and bacterial infections of the urinary tract.

DOSAGE: Dogs-25 mg/lb body weight every 6 hours via oral administration.

WARNING: Not for use in animals which are raised for food production. Chloramphenicol products should not be administered in conjunction with or 2 hours prior to the induction of general anesthesia with pentobarbital because of prolonged recovery.

Read package insert carefully before use.

Store at or below 25°C (77°F) in a dry place.

LOT:
EXP:

VICETON

chloramphenicol tablet, coated

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|----------------|
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:12487-2210 |
| Route of Administration | ORAL | DEA Schedule | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| Chloramphenicol (UNII: 66974FR9Q1) (Chloramphenicol - UNII:66974FR9Q1) | Chloramphenicol | 1 g |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | yellow | Score | 2 pieces |
| Shape | OVAL | Size | 6mm |
| Flavor | | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|-----------------------|--|---------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:12487-2210-1 | 100 in 1 BOTTLE | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| NADA | NADA055059 | | 06/23/1975 | |
| | | | | |

| VICETON | | | | |
|--|--|---------------------|----------------------|--------------------|
| chloramphenicol tablet, coated | | | | |
| | | | | |
| Product Information | | | | |
| Product Type | PRESCRIPTION ANIMAL DRUG | | Item Code (Source) | NDC:12487-2212 |
| Route of Administration | ORAL | | DEA Schedule | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| Chloramphenicol (UNII: 66974FR9Q1) (Chloramphenicol - UNII:66974FR9Q1) | | | Chloramphenicol | 250 mg |
| | | | | |
| Product Characteristics | | | | |
| Color | yellow | Score | 2 pieces | |
| Shape | ROUND | Size | 10mm | |
| Flavor | | Imprint Code | | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:12487-2212-1 | 500 in 1 BOTTLE | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| NADA | NADA055059 | | 06/23/1975 | |
| | | | | |

| VICETON | | | | |
|--------------------------------|--|--|--|--|
| chloramphenicol tablet, coated | | | | |
| | | | | |
| Product Information | | | | |

| | | | |
|-------------------------|--------------------------|--------------------|----------------|
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:12487-2213 |
| Route of Administration | ORAL | DEA Schedule | |

| Active Ingredient/Active Moiety | | |
|--|-------------------|----------|
| Ingredient Name | Basis of Strength | Strength |
| Chloramphenicol (UNII: 66974FR9Q1) (Chloramphenicol - UNII:66974FR9Q1) | Chloramphenicol | 500 mg |

| Product Characteristics | | | |
|-------------------------|--------|--------------|----------|
| Color | yellow | Score | 2 pieces |
| Shape | ROUND | Size | 13mm |
| Flavor | | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|---------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:12487-2213-2 | 500 in 1 BOTTLE | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| NADA | NADA055059 | 06/23/1975 | |

Labeler - Osborn (043653216)

Registrant - Bimeda Inc Division of Cross Vetpharm Group Ltd (060492923)

| Establishment | | | |
|---|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Bimeda Inc Division of Cross Vetpharm Group Ltd | | 060492923 | manufacture |

| Establishment | | | |
|-------------------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| YangZhou Pharmaceutical, Ltd. | | 544854599 | api manufacture |